REMARKS

The present amendment is in response to the Advisory Action mailed January 5, 2011, and supplements the previous Amendment And Reply Under 37 CFR §1.116 dated December 23, 2010 in response to the Final Office Action mailed October 27, 2010. The present amendment has been made based on the claims filed in the Amendment dated December 23, 2010, which was entered as indicated in the electronic file wrapper of the present application. Applicants respectfully request that the Examiner consider the present amendment and the following remarks as addressing the Advisory Action of January 5, 2011 and the rejections set forth in the Final Office Action of October 27, 2010.

After entry of this amendment, claims 1-14 and 64-69 are pending, of which claims 7-9 are withdrawn. New claims 67-69 have been added and find support *inter alia* in the original claims. Further support for new claims 67-69 is found in the specification, for example, at page 75, line 34, through page 76, line 14. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. Claim 1 finds further support in the specification, for example, at page 75, line 34, through page 76, line 14, and page 89, line 35, through page 90, line 29. Claim 6 finds further support in the specification, for example, at page 75, line 34, through page 76, line 14. No new matter has been added.

Applicants enclose herewith a Request for Continued Examination requesting entry of the above claim amendment and consideration of the present remarks. The above claim amendment and following remarks address the rejections in the Final Office Action dated October 27, 2010 and also the comments in the Advisory Action mailed January 5, 2011.

Rejoinder Request

Applicants respectfully request rejoinder of withdrawn claims 7-9 for the reasons stated in the Response dated December 23, 2010, which is repeated below for the Examiner's convenience.

Withdrawn claims 7-9 depend directly from claim 1 and as such, further narrow the scope of the base claim. For example, claim 7 is drawn to a process for the production of compounds of the general formula I as recited in claim 1, wherein the process further comprises introducing a nucleic acid sequence encoding a polypeptide with ω3-desaturase activity. Similarly, claim 8 is drawn to a process for the production of compounds of the general formula I as recited in

claim 1, wherein the process further comprises introducing a nucleic acid sequence encoding a polypeptide with Δ12-desaturase activity. Likewise, claim 9 is drawn to a process for the production of compounds of the general formula I as recited in claim 1, wherein the process further comprises introducing a nucleic acid sequence encoding a protein of fatty acid or lipid metabolism biosynthetic pathway. Thus, the subject matter of claim 1 and the subject matter of withdrawn claims 7-9 are related and not independent because they are disclosed as connected in at least one design, operation, or effect. Accordingly, restriction between these claims would be improper.

Moreover, because these withdrawn claims are drawn to the same subject matter as recited in claim 1, Applicants believe that there would be no extra burden on the Examiner to consider these claims together with claim 1 in the present application.

For at least the above reasons, Applicants respectfully request reconsideration and rejoinder of withdrawn claims 7-9.

Double Patenting

Claims 1-6, 10-14 and 64-66 are provisionally rejected for obviousness-type double patenting over claims 1, 2 and 5-11 of co-pending Application No. 10/566,944. Because this is a provisional double patenting rejection, Applicants will consider filing an appropriate terminal disclaimer upon an indication that the claims are allowable.

Claim Rejections – 35 U.S.C. § 112

Claims 1-6, 10-14 and 64-66 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and for alleged lack of an enabling disclosure. Applicants respectfully disagree. However, to expedite prosecution, the claims have been amended without prejudice or disclaimer to recite the claimed subject matter with more specificity. Applicants respectfully submit that the claims as amended overcome both rejections for the reasons already of record and for the following additional reasons.

Written Description Rejection

Claims 1-6, 10-14 and 64-66 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description support. Applicants strongly disagree in view of the present amendment and for the following reasons.

The "written description" requirement under 35 U.S.C. § 112, first paragraph, serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005); *see also* MPEP § 2163. Possession may be shown in a variety of ways including description of an actual reduction to practice. *See* MPEP § 2163 (citation omitted). For a claimed genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

It is noted initially that the specification describes a polypeptide with the specified Δ5-elongase activity having the amino acid sequence of SEQ ID NO: 68, 84, or 114 by their actual structure (i.e. sequence, a reduction to practice). Because the genetic code and its redundancies were known in the art at the time of filing, the disclosure of SEQ ID NO: 68, 84, or 114, combined with the pre-existing knowledge in the art, would have put a skilled artisan in possession of the genus of nucleic acids that encodes SEQ ID NO: 68, 84, or 114. Additionally, with the aid of various computer programs available at the time of filing, one skilled in the art could have identified all of the nucleic acids that encode polypeptides with at least 50% sequence identity with SEQ ID NO: 68, 84, or 114. Thus, the presence of an amino acid sequence that is at least 50% identical to SEQ ID NO: 68, 84, or 114 on the amino acid level is a structural feature of each of the proteins within the claimed genus. Because the level of skill and knowledge in the art is such that one of ordinary skill would be able to make and identify variants or homologues having 50% identity to SEQ ID NO: 68, 84, or 114 on the amino acid level routinely, those skilled in the art would conclude that Applicants were in possession of the claimed genus at the time the application was filed. See, "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement," at page 37-38.

Similarly, with the aid of various computer programs available at the time of filing, one skilled in the art could have also identified all of the nucleic acids with at least 50% sequence

identity with SEQ ID NO: 67, 83, or 113. Thus, the presence of a polynucleotide sequence that is at least 50% identical to SEQ ID NO: 67, 83, or 113 on the nucleic acid level is another structural feature of each of the nucleic acid sequences within the claimed genus. Because the level of skill and knowledge in the art is such that one of ordinary skill would be able to make and identify variants or homologues having 50% identity to SEQ ID NO: 67, 83, or 113 on the nucleic acid level routinely, those skilled in the art would further conclude that Applicants were in possession of the claimed genus at the time the application was filed.

Likewise, as understood by one skilled in the art, a variant of a nucleic acid is a homologue of such a nucleic acid that has any change in the polynucleotide sequence relative to the reference sequence. As provided in the specification, variants of SEQ ID NO: 67, 83, or 113 encompass, for example, any nucleic acid that is at least 50 or 60%, preferably at least approximately 60 or 70%, more preferably at least approximately 70 or 80%, 90% or 95% and even more preferably at least approximately 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or more identical to SEQ ID NO: 67, 83, or 113. See e.g., Specification at page 89, line 35, through page 90, line 29. Similarly, as described in the specification, variants of SEQ ID NO: 68, 84, or 114 encompass, for example, any polypeptide that is at least 50%, preferably at least approximately 60% and more preferably at least approximately 70%, 80% or 90% and most preferably at least approximately 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or more identical to SEQ ID NO: 68, 84, or 114. See e.g., Specification at page 75, line 34, through page 76, line 14. In view of the level of skill and knowledge in the art, together with the methodologies and tools available at the time of filing, one skilled in the art would be able to easily identify and isolate variants of SEQ ID NO: 67, 83, or 113, or variants of SEQ ID NO: 68, 84, or 114, routinely. Thus, those skilled in the art would conclude that Applicants were in possession of the claimed genus at the time the application was filed.

Additionally, the specification, by way of working examples, shows that the claimed process produces the compounds as recited in the claims (e.g., Examples 60 and 61). The specification, therefore, provides a description of an actual reduction to practice as to the claimed processes as well. As such, one skilled in the art, reading the specification, would reasonably conclude that Applicants were in possession of the subject matter that is now claimed at the time

of filing. Accordingly, the written description requirement is further satisfied for this additional reason.

For at least the above reasons and for the reasons already of record, and further in light of the present amendment, it is respectfully submitted that the specification provides adequate written description for the claims as amended. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Separate consideration to newly added claims 67-69 is further respectfully requested.

Enablement Rejection

Claims 1-6, 10-14 and 64-66 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of an enabling disclosure. Applicants strongly disagree in view of the present amendment and for the following reasons.

As acknowledged by the Examiner, the specification is enabling for SEQ ID NO: 67 or a sequence encoding SEQ ID NO: 68. The specification further discloses other polypeptides with the specified Δ5-elongase activity (e.g., SEQ ID NO: 84 and 114). Moreover, as discussed in Applicants' Response dated December 23, 2010, the specification provides detailed guidance, including working examples, on how to make and use the claimed subject matter.

For instance, as discussed previously, the specification provides in detail, by way of working examples, how to isolate a Δ5-elongase gene from various species (e.g., Examples 10, 14, 19, 43, and 48), how to clone and overexpress such a gene in yeast (e.g., Examples 11, 15, 20, 44, and 49), and how to determine the effect of such an overexpression in yeast (e.g., Examples 13, 18, 23, 47, and 51). The specification further provides detailed guidance as to how to clone various genes in plasmid for expression in plants (e.g., Examples 12, 16, 21, 45, and 57), how to generate transgenic plants expressing various genes of fatty acid biosynthesis pathway (e.g., Example 58), and how to determine the effect of such an overexpression in the seeds of transgenic plants (e.g., Examples 60 and 61). Although only a few Δ5-elongases with the recited activity are exemplified in the working examples, Applicants respectfully submit that those procedures and techniques are equally applicable to identify other nucleic acid sequences encoding Δ5-elongases within the scope of the present claims. Thus, one skilled in the art would be able to identify a nucleic acid coding for a Δ5-elongase having the specified activity without undue experimentation.

Moreover, as described in the specification and known in the art, sequences having at least 50% identity to SEQ ID NO: 67, 83, or 113, or the encoded amino acid sequence of SEQ ID NO: 68, 84, or 114, can be determined by using mathematical algorithms such as PILEUP, GAP and BESTFIT, as described in the specification (see e.g., Specification at page 23, lines 30-38), or BLAST, FASTA, TFASTA, and CLUSTALW, as well known in the art at the time of filing. Accordingly, one skilled in the art would be able to easily identify a sequence that is within the scope of the claims and use the art-recognized screening and testing techniques such as those provided in the specification to determine whether a nucleic acid having at least 50% identity to SEQ ID NO: 67, 83, or 113, or one encoding a polypeptide with at least 50% identity to SEQ ID NO: 68, 84, or 114, has the required characteristics (i.e. the recited Δ5-elongase activity).

Additionally, methods for generating, identifying and isolating variants of a nucleic acid are well known in the art and routinely used by one skilled in the art. For instance, site-directed mutagenesis may be used to introduce mutations into a particular sequence. With the aid of comparative algorithms, such as those mentioned above, the difference between such a variant and the reference nucleic acid could be easily identified. Using routine techniques such as those provided in the specification as discussed above, one skilled artisan would be able to test and determine whether such a variant possesses the specified Δ5-elongase activity. As exemplified in the specification, all of these techniques are ready available and routinely used by one skilled in the art.

Thus, in view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the claims as amended without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). It is further noted that the above analysis is also consistent with the Board's decision in *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007), *aff'd on other ground*, 90 USPQ 2d 1417 (Fed. Cir. 2009), where the Board noted that, even though practicing the full scope of the claims might have required extensive experimentation, the experimental techniques were well-known in the art, so the experimentation would have been routine and thus, not undue. *Id.* at 1416. In this case, the required experimentation would not be extensive and is routine in nature.

For at least the above reasons and for the reasons already of record, and further in light of the present amendment, it is respectfully submitted that the present claims as amended recite a

scope of subject matter which a skilled artisan could clearly make and use according to the teaching in the specification. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Separate consideration to newly added claims 67-69 is further respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Accompanying this response is a Request for Continued Examination to respond to the Office Action mailed October 27, 2010 with the required fee authorization. No further fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13987-00020-US from which the undersigned is authorized to draw.

Respectfully submitted,

By /Hui-Ju Wu/

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